



MAY 2005

HOW TO DO BUSINESS IN JAPAN

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Overview of Asia and its Medical Device Markets

Demographics (2004)

Country	Population	Population Growth (2004 est.)	GDP (PPP)	Per Capita Income (PPP)	Life Expectancy (Years)
China	1,298,847,624	0.57%	6.449 trillion	5000	71.96
Hong Kong	6,855,125	0.65%	212.2 billion	28,700	81.39
Philippines	86,241,697	1.88%	390.7 billion	4,600	69.6
Indonesia	238,452,952	1.49%	758.1 billion	3,200	69.26
Japan	127,333,002	0.08%	3,567 trillion	28,000	81.04
Malaysia	23,522,482	1.83%	207.2 billion	9,000	71.95
Singapore	4,353,893	1.71%	109.1 billion	23,700	81.53
Korea	48,598,175	0.62%	855.3 billion	17,700	75.58
Taiwan	22,749,838	0.64%	528.6 billion	23,400	77.06
Thailand	64,865,523	0.91%	475.7 billion	7,400	71.41

Healthcare Statistics (2003)

Country	Number of Hospitals	Doctors per 1000 Persons	Per Capita Spending on Healthcare (US\$)
China	330,348	1.69	30
Hong Kong	103	1.4	N/A
Philippines	1,652	N/A	33
Indonesia	1,089	0.14	19
Japan	169,556	1.91	2,908
Malaysia	360	0.7	101
Singapore	28	1.39	4,107
Korea	21,686	1.35	584
Taiwan	18,265	7.42	677
Thailand	1,392	0.32	71

Medical Device Market Sizes

Country	Medical Device Market Size
China	US \$3.5 billion
Hong Kong	US \$500 million
Philippines	US \$75 million
Indonesia	US \$150 million
Japan	US \$24 billion
Malaysia	US \$300 million
Singapore	US \$410 million
Korea	US \$1.4 billion
Taiwan	US \$900 million
Thailand	US \$500 million

Asian Medical Device Markets

- Over 30% of new expenditures on healthcare worldwide is attributable to Asia
- Spending is driven by:
 - Aging population
 - Increasing life expectancy
 - Increasing incidence of major diseases
 - Increasing health consciousness
 - Higher disposable income

Major Markets in Japan

- Southern Kanto region
 - Tokyo, Chiba prefectures
- Kansai region
 - Osaka, Kyoto,
Hyogo prefectures
- Tokai region
 - Aichi, Gifu prefectures

Market Research

Overview

- Is there a demand for your product? If it sells here in the U.S., that does not mean it will sell in Asia
 - How do you do market research?
 - Real primary research is the way to go

How do your competitors do business?

- In addition to conducting primary market research
 - Determine how your competitors do business
- How do competitors distribute to:
 - Doctors
 - Clinics
 - OEMs
 - Hospitals
- Does competitor export products and use local distributors? Have local manufacturing capabilities and their own sales forces?

Finding the Right Distributor

Finding the Right Distributor in Asia

- Use the same criteria as you would for a distributor search in the rest of the world
- In Asia, relationships and trust are key
 - Not lawsuits!
 - Need introductions? How do you do this?

Japan Distributor Search

- Finding a Japanese distributor takes longer than in other Asian countries
- Relationships with the Japanese may take several years to develop
 - Move slowly
 - Build trust
- Keiretsu sales
- Raincoat story

Distributor Overview

- Good distribution network is fundamental to the success of U.S. medical manufacturers exporting to Asia
- Distributors generally provide:
 - Warehousing and shipping
 - Sales and marketing
 - Service support for products being sold
- Manufacturers must consider:
 - Goals and expectations
 - Cultural differences
 - Integrity of distributor
 - Legal specifications of contract
- What works in the U.S and Europe does not suffice in Asia

Finding the Appropriate Distributor

- Seek out distributor that sells similar products by:
 - Determining with which distributors the local hospitals conduct successful business
 - Hiring a consultant with experience in the region
- Background check of distributor's reputation is a must
- Manufacturers can contact other medical manufacturers that already employ prospective distributor or well-connected local sources for information
- Determine amount of time and effort distributor is willing to spend with your products

Establishing A Good Relationship With A New Distributor

- Asians put their trust in personal relationships, which take time to develop
- Introductions from friends, colleagues, or classmates is key
- Asian distributor who does not have personal connection with manufacturer may:
 - Misrepresent himself
 - Copy manufacturer's technology
 - Cheat the manufacturer
 - Reputation is not on the line as it would be with a personal connection

Drafting the Contract

- In Japan -
 - A contract is a loose agreement to do business; not a document detailing every aspect of the business relationship
 - Does not guarantee that the business relationship is good
 - Prefer to sign short agreements stating that they will do business, leave details for later
 - Personal commitments have a far greater meaning

- In the West, lengthy contracts with an attention to detail are most typical
 - U.S. manufacturer might find itself discussing points of contention, such as sales targets and product service clauses, after contract is signed

- Contract will need to be adapted to account for the differences in each country's culture and legal system

- Exclusive vs. Non-exclusive: Decision is a function of the manufacturer's goals and size of territory

Setting A Sales Quota

- Sales quota specifies distributor's responsibility to purchase a minimum amount of product per year
- Helps ensure than exclusive distributor will meet manufacturer's sales targets
- U.S. manufacturers should not be too hasty about terminating a relationship with a distributor who does not exactly meet a sales target
 - Continuing the partnership signals trust in the distributor, who may make an effort to make up the missed sales the next year

How To Resolve Distributor Problems

- Manufacturers should recognize benefits of working toward mutually beneficial long-term relationship
 - Do not fire a distributor too quickly
- U.S. manufacturers who decide to end partnerships with distributors:
 - May find they have acquired a tarnished reputation in that country
 - Once a reputation is sullied in Asia →
 - Other potential distributors in that country may hesitate to carry the manufacturer's products
- When difficulties arise:
 - Personal solutions more acceptable than legal ones
 - Face-to-face visits are usually well received
 - Faxes considered impersonal; miscommunication possible
- Arbitration clauses in contract

Company Examples

- Visible Genetics Inc. (VGI; Toronto, Canada) and Roche Diagnostics K.K. (RDKK; the Japanese subsidiary of Switzerland-based Roche AG)
 - Established agreement whereby RDKK would be exclusive distributor in Japan for some of VGI's products
- PLC Systems Inc. (Franklin, MA) renewed distribution agreement in Japan with Imatron Japan Inc.
 - Agreement for PLC to distribute medical products in Japan for Imatron Inc. (San Francisco, CA)

What kind of office can you
set up in Japan?

Options For Foreign Companies

- Representative office
- Branch office
- Subsidiary corporation
- Joint venture

Representative/Liaison Office

- Simplest form of business structure
 - Usually one person with assistant
 - Established in preparation for future expansion into branch or subsidiary
 - All activities must support and represent parent company
- Functions
 - Advertising
 - Public relations
 - Market research
 - Monitor activities of Japanese distributors/agents handling parent company's products
 - Cannot sell or conduct any “real business”
 - cannot generate any profits

Branch Office

- Requires simple registration process
 - Registration fee
 - Filing the company's representative "seal"
 - Registering tax and related expenses items
 - Submitting proxy notifications
- Must appoint an official representative responsible for local operations
 - Does not have to be a Japanese citizen, but must be a legal resident of Japan
- Branch offices can earn income and remit to parent company
 - Can also be established to conduct activities that do not generate income
- Subject only to income tax on Japan source net income only
 - Deduction can be claimed for reasonable head office expenses
 - Profits can be remitted to home office; not subject to withholding tax
- Good option if losses are expected – may be included in U.S. federal tax return

Subsidiary Corporation

Kabushiki Kaisha (KK)

- A KK is similar to U.S. public corporation, though not listed on the stock market
 - Often wholly owned
- Advantages:
 - Easier to arrange local financing, lease office space, attract local employees
 - Prestige
 - Indicates long-term commitment
 - Limited liability
 - Freely transferable shares
 - Well-defined procedures of establishment and management
- Requirements
 - Minimum capital of approx. \$100K
 - 25% of shares must be issued
 - Three directors; at least one must reside in Japan

Practical Issues

- Finding office space
 - Location
 - Prestige
 - Cost
- Key money

Other Possible Business Structures

- Options for a one-person operation
 - U.S.-based office
 - Japanese home-based operation
 - Office at a distributor
 - Subletting in a U.S. office
 - Shared executive office
 - Independent office

Other Possible Business Structures

- Use the resources of another foreign company already in Japan
 - For small or medium size companies that do not have the resources to manage distributors or set up a marketing JV on their own
- Use direct marketing
 - Marketing through mail order catalogues or on the Internet is becoming more popular in Japan
 - Must follow specific government regulations

Other Possible Business Structures

- Setting up a manufacturing facility in Japan
 - Companies expecting a large Japanese market for their product should consider setting up a facility or manufacturing JV
 - Benefits:
 - Products made locally and can be easily modified to meet needs of Japanese market with input from local medical community
 - Reduces time to market

Company Example

- **GE Medical Systems** (Waukesha, WI) - leading provider of medical diagnostic equipment and services
- **NEC Medical Systems** - develops and manufactures patient monitors, cardiovascular equipment and cerebral nerve equipment
 - GE Medical acquired Japanese distribution operation from NEC Medical, a wholly-owned subsidiary of medical diagnostic NEC Corporation
 - GE Medical and NEC Medical will form a joint marketing and distribution network for both companies' products and services
 - GE will hold a majority stake in the venture
 - NEC Medical will design, develop and provide the new company with medical products manufactured at NEC Medical's facility in Gunma, Utsonomiya, Japan
 - NEC Medical's Japanese sales offices and sales staff of 300-350 in Japan will be transferred to the joint operation

Joint Venture

- Japanese government outlook on JVs
 - Situation improving for foreign companies in Japan
- Must be approved by Ministry of Finance
- JV staff
- Head office support
- Foreign manager
 - Familiarity with own company, JV and Japanese culture, lifestyle
- Potential problems
 - Establishing mutual confidence
 - Communication
 - Winning overall support

Keiretsu Kaisha

- Groups of allied corporations; includes manufacturers, suppliers, distributors, financial institutions, etc.
- Many international corporations work in keiretsu groups
- Small companies may gather around keiretsu kaishas for added business security and profits
 - If successful, gain easier access to all other members of keiretsu
 - Also subject to demands of keiretsu corporations; could be cut out of keiretsu and lose business from all member corporations if these demands are not met

Staffing Your Office

Current Situation in Japan

- Economy has struggled since Asian currency crisis
 - Mild recovery period 2003-2004
- Aging population
 - Working-age population declining
 - Persons 65+ make up about 20% of population
 - Decreasing fertility rate
- Few Western business schools, MBAs

Overview of HR Practices

- Lifetime employment
 - Traditional, long-term form of hiring
 - Employees work at same company from graduation until retirement
 - Training throughout career; often rotated/transferred within company
 - Builds loyalty, good working relationships
 - Some companies moving away from lifetime employment (in Tokyo, Osaka)
 - Hiring more non-regular employees, such as part-time workers
 - Save money by reducing the overall number of hours worked by employees
- Compensation
 - Seniority-based:
 - Traditional system; based on age, years worked; emphasizes chain of command
 - Merit-based:
 - Newer system; based on productivity and quality of work
 - Encourages productivity, achievements
 - Salaries - paid in 14 equal parts (12 months + 2 bonuses)

Recruiting

- Strategies vary depending on type and size of company
 - Large companies:
 - University recruiting
 - Usually offer lifetime employment and on-the-job training
 - Smaller companies:
 - Cannot always offer high wages and stability
 - Hire more mid-career workers
 - Foreign companies:
 - Newspaper advertisements in Japanese and English
 - Word of mouth
 - Employment agencies
- Things to consider:
 - Language: Foreigners with no Japanese skills unlikely to be hired by domestic companies
 - Women: Few domestic management positions
 - Colleges and universities: Most popular source of hiring for major companies; difficult for foreign companies to compete
 - Hiring returnees: Could be less expensive than Expats

Basic Regulatory Issues for Medical Devices

MHLW

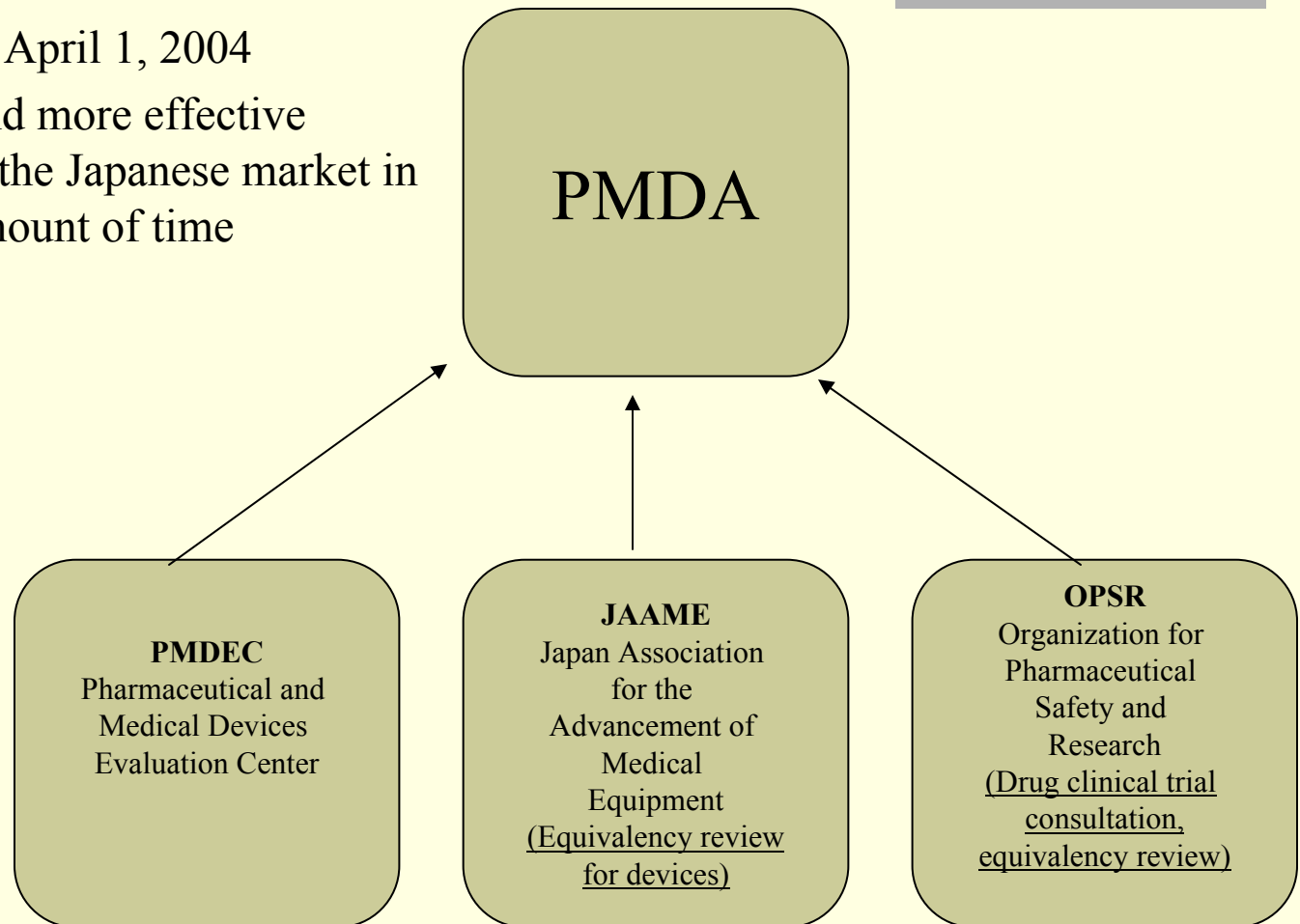
(Ministry of Health, Labor and Welfare)

- Some of the areas regulated by the MHLW:
 - Pharmaceutical, medical device and food regulations and safety (including PMDA and PAL)
 - Healthcare services
 - Employment and labor standards
 - Pension and health insurance

PMDA

(Pharmaceutical and Medical Device Agency)

- Established April 1, 2004
- Get safer and more effective products to the Japanese market in a shorter amount of time



Improved Measures Through the PMDA

- Creation of a system for consultation with the MHLW
 - Reduces time to submission
 - Improves quality of applications
- More medical specialists to review drug and device applications
 - Shorter review time by PMDA
- Products get to the marketplace faster
 - Better for companies
 - Better for patients

New PAL

(Pharmaceutical Affairs Law)

- Some of the major changes:
 - MAH system
 - Risk-based medical device classification system
 - New/additional requirements for device registration process (i.e. STED – Summary Technical Documents)
 - New GMP similar to ISO 13845:2003
 - New design control requirements
 - Inspections

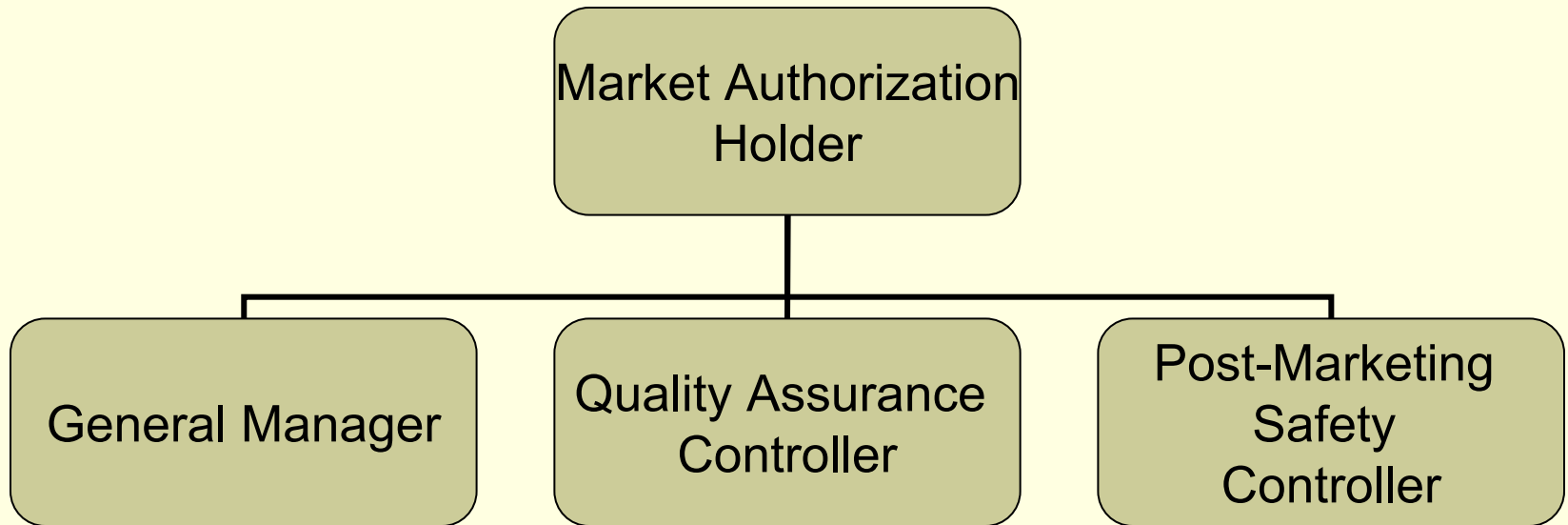
MAH Overview

- MAH system separates manufacturing and product release
 - Increases quality and safety controls
 - Devices are more closely regulated like drugs
- MAH Responsibilities:
 - Purchase or import products from a manufacturer
 - Sell products to sales groups
 - Sometimes temporarily store products in a MAH-licensed establishment

Designating a MAH

- All companies selling devices in Japan must have a MAH
- MAH must be located in Japan
- A company can designate a distributor/importer, 3rd party, or themselves as their MAH
- If designate themselves →
 - A subsidiary, branch, or representative office in Japan can be their MAH, as long as the MAH meets the MHLW's requirements

MAH Structure



Three Controllers

1. General Manager

- Oversees all MAH duties, including GQP and GVP

2. Quality Assurance Controller

- Responsible for GQP
- Ensure that manufacturer follows proper methods for shipping and receiving
- Notify MHLW of any changes in manufacturing or in-process controls
- Develop release criteria for each product
- Handle communication in the case of a recall

3. Post-Marketing Safety Controller

- Responsible for GVP
- Monitor safety of products released into the market
- Provide reports to health authorities on adverse incidents, recalls, etc.

Controller Requirements by Device

CLASSIFICATION

CONTROLLER(S) NEEDED FOR A MAH

General Devices

One person can serve as all three Controllers

Controlled Devices

Two Controllers required:
One serves as GVP, the other as the GQP;
the GVP or GQP will also be the GM

Highly Controlled
Devices

Three separate people required, each serving
as one Controller

MAH Costs

- Costs vary depending on company's status in Japan - already established vs. entering the market for the first time
 - Example #1:
 - Monthly retainer: \$3K - \$4K
 - PLUS
 - % of sales
 - Example #2:
 - Flat monthly fee of approximately \$6K - \$8K
- Retainer fee covers MAH services previously mentioned, such as GQP, GVP, MAH personnel, product storage, adverse effect reporting, etc.
- Other MAH services, such as product application preparation/registration, translation work, labeling development, etc., require additional fees

MAH Strategies for Foreign Companies

- Foreign companies should develop their MAH strategy based on their current or expected sales in Japan
- Sales less than \$500,000 per year:
 - Would most likely see the independent MAH fees eating into their profit margins
 - If the company does not want to put their confidential product information at risk by using a distributor, they may decide to not enter Japan at all
- Sales around \$500,000 to \$2 million per year:
 - Pay for independent third party to serve as their MAH in order to better protect their confidential information (versus using a distributor) and retain more control of their product marketing
- Sales over \$2 million:
 - May choose to establish their own MAH

Intellectual Property

- IP protection more difficult than in the US
 - But better in Japan than in other Asian countries
- Copyrights
 - Expires 50 years after author's death
- Trademarks
 - Whoever applies for a trademark first, owns it
 - Current producer/marketer of the product is not relevant

Patents

- Japan Patent Office (JPO) in charge of granting patents
- Two basic elements: administration and enforcement
 - Administration covers patent applications, processing, denials or grants
 - JPO receives and examines applications that contain a "written description of the invention and set of claims," including the technological scope of the inventions
- Courts are the primary arbitrator of patent disputes
 - JPO also vested with enforcement capabilities

	Japan (JPO)	United States (PTO)
Patent Granting	First-to-file	First-to-invent
Language used in filing	Japanese or English if Japanese translation is provided within 3 months	Any
Publication of patent	After patent granted Application	After patent granted
Deferred patent examination	May be deferred for up to 7 years	No
Opposition system	After a patent is granted, other parties can request a re-examination	No
Grace period for examination	Yes (6 months)	No

Types of Regulatory Resources Available in Japan

- Finding and evaluating regulatory assistance is not easy in Japan
- Limited number of ways employees can receive medical regulatory training; very few formal educational programs for this type of training in Japan
- Most people gain expertise in Japanese medical regulations through working in regulatory departments of medical device companies, employment at regulatory consulting companies, or at the MHLW
- Regulatory resource options in Japan
 - Consultants
 - Hiring your own regulatory employees
 - Market Authorization Holders (MAHs)
 - Contract Research Organizations (CROs)

Some Important Cultural Issues

Western Approach	Asian Approach
Do a deal	Build relationships
Maximize short-term profits	Establish long-term foundations
Be frank	Don't deliver bad news
Make changes quickly	Move when ready

A Different Way of Thinking

- Use and View of Time
 - Americans – minute/hour
 - Japanese – event/season
 - Events move forward when *group* is ready
- Relationships
 - Company to company
 - Person to person (how business relationships develop)
 - Family relationship
 - Most successful Japanese companies keep records of client information (birthdays, anniversaries, etc.) and sent cards
- Japanese Logic
 - Often based on emotion rather than reason
- “Group” and “Individual”
 - Group consensus – no single person should be targeted
 - Emphasis on company spirit
- When Things Go Wrong
 - Apology is very important

Social Interactions

- Japanese society has a carefully-defined hierarchy; this structure extends into the corporate world
- Japanese also identify themselves as members of a group (i.e. family group, work group)
 - Groups are defined based on the situation, example:
 - Foreigner and Japanese counterpart of same company meet to do business →
 - If business goes well, Japanese counterpart may consider foreign as a member of his group
 - If problems or disagreements arise, Japanese may consider foreigner an outsider
- *Face*:
 - Person's *face* represents their company, even during non-business hours
 - One should be careful never to criticize or offend – this could cause loss of face and could ruin a business relationship

Holding a Meeting

- Planning
 - Time is money
 - Appointments/meetings should be scheduled in advance
- Introductions
 - Rank Determines Order of Introductions
 - Senior leaders introduced first (handshake with foreigners, bow between Japanese)
 - Business Cards (*meishi*)
 - Should be given to each member of the other delegation
 - Present and receive with both hands, taking a moment to read each card
 - Treat card with care – do not write on card or toss in briefcase
- Corporate Materials
 - Summary of company information; short bio of President/Chairman
 - Press clippings/third party endorsements
 - All items should be professionally translated into Japanese
 - Packets/kits should be distributed to each member of the meeting

Holding a Meeting

(Continued)

- The Meeting
 - Seating Arrangements
 - Attitude and Direct Communication
 - Language
 - Interpreters
 - Negotiating
 - About Your Negotiator

Decision-making

- Japanese companies make decisions by consensus; decisions are rarely made by a single individual
- Takes much longer for a decision to be made than in US companies
 - Suggestion/proposal circulated for approval
 - Many unnecessary meetings
 - In negotiations, management usually does not have the authority to make decisions
 - Difficult for them to deal with people at Western companies
- Advantages:
 - Decision-making process involves employees from many levels of company hierarchy
 - Breeds loyalty, good relations, provides employees with experience
 - Once a decision is made, it is usually a good one and is easier to implement

Dispute Resolution

- Lawsuits are uncommon in Japan
 - Thought to impede “social harmony”
 - If a legal dispute arises, usually settled by informal negotiation, not a lawsuit
 - Most contract breaches are forgiven
 - Contract terms may be renegotiated
-
- If negotiation does not work → Arbitration

Arbitration

- Used instead of negotiation, while still avoiding litigation
- Tends to be long and expensive
- Usually held before the Japan Commercial Arbitration Association (JCAA) in Japan
 - Arbitrators are almost always Japanese
- If outside Japan
 - American Arbitration Association or International Chamber of Commerce may be used

Recreation and Business

- Important for establishing personal relationships with Japanese counterparts
- Japanese businessmen are notorious “social drinkers”
- Limit business talk during recreation
- Complex order regarding where to go and what kind of entertainment to partake in depending on rank of counterparts

Little Things That Mean A Lot

- Bowing
 - Traditional greeting, though handshake is more common
- Shoes
 - Should be removed in some restaurants and most homes
- Gifts
 - Honored guests usually presented with a gift
 - Businesses should have high quality, but not too expensive gift for other company
 - Gift should be wrapped and presented with both hands